Remarks

35 U.S.C. § 103 Rejection

Claims 1-4 were rejected under 35 U.S.C. § 103 as being unpatentable over Rowinsky et al.

Claims 1-4 are directed to a method of treating lymphoma or breast cancer with infusion of a taxol solution of low dosage over an extended period of time. Specifically, claims 1-4 relate to the treatment of lymphoma or breast cancer via infusion of between 17.5 and 35 milligrams of taxol per square meter of patient surface area per 24 hours, for a period of approximately 96 hours.

The Examiner contends that Rowinski discloses the use of taxol for 24 hours at 200-250 mg/m^2 by infusion, and that one skilled in the art could employ the infusion solution of the prior art for a longer period of time.

Applicants respectfully submit that Rowinsky does not teach or suggest the use of taxol as disclosed by Applicant's invention. Rowinsky teaches the use of taxol infused at a rate of 200, 250, 315, and 390 mg/m^2 over a 24 hour period (Rowinski 4642). And Rowinski specifically states that patients less heavily pretreated with other mucosal toxins before taxol infusion "may be able to tolerate significantly higher taxol doses" (Rowinski, p. 4644), suggesting the use of higher doses in a 24 hour period.

The chart below compares Rowinski's method to Applicants:

	Rowinski	Applicants	Applicants Dose And Time as % of Rowinski
Dose/24 hours	200-250 mg/m^2	35 mg/m^2	14-17%
Treatment Time	24 hours	96 hours	400%

While the prior art teaches the infusion of high doses of taxol over a 24 hour period, Applicants' method employs a taxol concentration 14-17% of that previously taught per 24 hour period. Additionally, Applicants' method involves an infusion time much longer than that used in the prior art.

Applicants' present invention discloses and claims the use of significantly lower doses of taxol - 17.5 - 35 mg/m^2/24hrs. - over a period of time in excess of 24 hours until remission of the lymphoma or breast cancer is attained. Applicants submit that by suggesting the use of higher doses of taxol per 24 hour period, the Rowinski reference teaches away from Applicants' invention and is therefore incapable of rendering the present invention obvious. See In re Dow Chemical Co., 837 F.2d 469, 5 USPQ2d 1529 (Fed. Cir. 1988); In re Hedges, 783 F.2d 1038, 1041, 228 USPQ 685, 687 (Fed. Cir. 1986) ("On balance, Hedges proceeded contrary to the accepted wisdom. This is 'strong evidence of nonobviousness'.").

Moreover, Applicants method of low dose taxol infusion over a long period of time provides a positive response in a far greater percentage of treated patients than the prior art (page 2, lines 23-33, page 9, line 20 to page 10, line 2), demonstrating the advantages of the present method.

Because the Rowinski reference fails to teach or suggest Applicants' invention of treating lymphoma and breast cancer with very low doses of taxol infused over an extended period of time, and there is no cited reference suggesting something intrinsic about the drug taxol that would suggest using a low dose over a longer period, Applicants respectfully request withdrawal of the § 103 rejection based on Rowinski et al.

35 U.S.C. § 112 (¶1) Rejection

Claims 1 and 2 were rejected under 35 U.S.C. § 112, first paragraph, because the term "cancer" lacks clear exemplary support in the specification.

Claim 1 has been amended to delete the broad term "cancer" and replace it with -- lymphoma and breast cancer --, for which there is support in the specification at page 5, lines 6-19, and page 9, lines 20-35.

35 U.S.C. § 101 Rejection

Claims 1 and 2 were rejected under 35 U.S.C. § 101 for being directed to non-statutory subject matter. The Examiner contends that there is insufficient evidence of record demonstrating that Applicants' taxol is effective for treating cancer broadly in patients.

Claim 1 has been amended to delete the term "cancer" and replace it with -- lymphoma and breast cancer --. Applicants submit that there is sufficient evidence of record (pp. 9-10 of specification) to support Claims 1 and 2 as amended, and respectfully request withdrawal of the § 101 rejection.

35 U.S.C. § 112 (¶2) Rejection

Claims 1-4 were rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Specifically, the Examiner contends that Claims 1-4 are improperly drawn to two different steps - the step of preparing an infusion solution and the step of infusion. Applicants have amended claim 1 to particularly point out and distinctly claim the present invention. Claim 1 is clearly directed to infusing a low dose taxol solution over a period of time taught by Applicants, until disease remission is observed. The functional limitation added to Claim 1 ("sufficient to cause remission of said lymphoma or breast cancer") finds support in the specification at pages 9-10.

Thus, Applicants' invention of treating lymphoma or breast cancer with long-term infusion of a low-dose solution of taxol is distinctly claimed in claim 1, as amended.

Applicants respectfully request withdrawal of the § 112, second paragraph, rejection.

In view of the amendment and remarks, Applicants respectfully submit that the instant application is in condition for allowance. Favorable action by the Examiner is earnestly solicited.

Respectfully submitted,

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